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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KRAMER, NICOLE R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,147	GOVARI, ASSAF	
	Examiner	Art Unit	
	Nicole R. Kramer	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 25-27* is/are pending in the application.

4a) Of the above claim(s) *6,7,9,14-17,21,22 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8,10-13,18-20,23,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 5, 8, and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication 2002/0095195 ("Mass et al.").

Mass et al. discloses an implantable medical device (100), the device comprising an outer casing comprising an insulating material (insulating material 102) and an electrically conductive material (metallic device housing halves 101a and 101b) and a transmitter encapsulated in the casing (RF drive circuitry 330 includes an RF transmitter and receiver; see paragraph 0014). Examiner considers the insulating material 102 to "surround" the metallic device housing halves 101a and 101b because the insulating material separates the housing portions from each other, and thus necessarily encloses or encompasses the entire, bottom perimeter or edge of each half. The transmitter is coupled to the conductive material so that the electrically conductive area of the casing serves as an antenna for transmitting the signal to a receiver outside the body (RF drive circuitry 330 is connected by a transmit/receive switch 333 to the dipole antenna formed by housing portions 101a and 101b; see paragraph 0014).

With respect to the claim limitation that the transmitter generates an electrical signal, the "signal being a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw, and roll orientations," Examiner notes that the medical device of claims 1 and 12 do not claim a position sensor for generating such a signal. Rather, claims 1 and 12 recite a type of signal that may be transmitted by the claimed transmitter, which is a recitation of intended use (that is, what type of signal the transmitter generates such that the signal can be transmitted to a receiver outside the body). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The transmitter circuitry of Mass et al. is capable of transmitting any type of sensed signal, including a position signal as in claim 1, and thus anticipates the claim. Alternatively, Examiner has provided an alternative 103 rejection below based on U.S. Patent Application Publication 2002/0095195 ("Mass et al.").

With respect to claim 3, Mass et al. discloses that the device housing is metallic (see paragraph 0013). Since the housing halves themselves are metallic, the electrically conductive material is necessarily arranged to fill an entire thickness of the casing between the inner surface and the electrically conductive area of the outer surface.

With respect to claim 5, Examiner notes that the recitation that "the electrically-conductive area is configured to contact a metal implant within the body of the

mammalian subject while transmitting the signal" is a statement of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The IMD of Mass et al. is capable of contacting a metal implant within the body, and thus anticipates claim 5.

With respect to claims 8 and 10-11, Mass et al. discloses that the IMD contains therapy circuitry, which may be used for physiological monitoring (see paragraph 0013). Physiological monitoring necessarily requires a sensor. As one example, Mass et al. describes a cardiac rhythm management device (i.e., a pacemaker) that includes sensing circuitry connected to electrodes for the control of heart rhythm (see paragraph 0014). Such sensing circuitry may be considered a sensor.

3. Claims 1-2, 4-5, 8, and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,861,019 ("Sun et al.").

Sun et al. discloses an implantable medical device (IPG 12) having a micro-strip or patch antenna (the patch antenna is formed of three layers: an electrically conductive, radiator patch layer 30/30', a conductive ground layer 48/48', and dielectric layer 36/36' sandwiched between the patch layer and the ground layer; see col. 10, lines 21-47) formed on the exterior surface of the housing or casing. Since the patch antenna is deposited on or embedded into the exterior surface of the IPG housing (see col. 10m lines 62-65), Examiner considers the patch antenna to be part of the

housing/casing. According, the IPG casing is considered to include an insulating material (dielectric layer 36/36') surrounding an electrically conductive material (electrically conductive patch radiator layer 30/30') and a transmitter encapsulated in the casing (telemetry transmitter 42 and receiver 44 are encapsulated within the IMD housing; see col. 9, lines 25-35). The transmitter is coupled to the conductive material so that the electrically conductive area of the casing serves as an antenna for transmitting the signal to a receiver outside the body (the radiator patch layer 30/30' is coupled to transceiver circuitry including transmitter 42 and receiver 44 within the IMD housing; see col. 9, lines 25-35).

With respect to the claim limitation that the transmitter generates an electrical signal, the "signal being a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw, and roll orientations," Examiner notes that the medical device of claims 1 and 12 do not claim a position sensor for generating such a signal. Rather, claims 1 and 12 recite a type of signal that may be transmitted by the claimed transmitter, which is a recitation of intended use (that is, what type of signal the transmitter generates such that the signal can be transmitted to a receiver outside the body). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The transmitter 42 of Sun et al. is capable of transmitting any type of sensed signal, including a position signal as in claim 1, and thus anticipates the claim. Alternatively,

Examiner has provided an alternative 103 rejection below based on U.S. Patent No. 5,861,019 ("Sun et al.").

With respect to claim 2, Sun et al. discloses that the dielectric material may be ceramic (see col. 13, lines 2-5).

With respect to claim 4, Sun et al. discloses an embodiment in which the electrically conductive radiator patch layer 30/30' is formed on the exterior surface of the ceramic housing 13' of the IPG, and ground layer 48' is formed as a conductive layer on the interior surface of the housing 13', such that the ceramic IPG housing constitutes and provides the dielectric substrate layer sandwiched between the ground layer and the radiator patch layer (see col. 15, lines 45-55). In such an embodiment, the conductive material (layer 30) is arranged in a layer overlying the insulating material (ceramic housing 13') as required by claim 4.

With respect to claim 5, Examiner notes that the recitation that "the electrically-conductive area is configured to contact a metal implant within the body of the mammalian subject while transmitting the signal" is a statement of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The IMD of Sun et al. is capable of contacting a metal implant within the body, and thus anticipates claim 5.

With respect to claims 8 and 10-11, Sun et al. discloses that data to be transmitted from the IPG to the external programmer includes sensor output signals (see col. 2, lines 8-25).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3, 5, 8, 10-11, 18, 23, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0095195 ("Mass et al.") in view of U.S. Patent No. 4,846,195 ("Alt") and further in view of U.S. Patent Application Publication 2002/0065455 ("Ben-Haim et al.").

As described above, Mass et al. discloses an IMD, such as a physiological monitor (see paragraph 0013) in which electrically conductive housing portions of the IMD casing form a dipole antenna. Mass et al. teaches that forming the antenna from conductive portions of the housing results in a greater bandwidth, which is easier to tune and is usable over a greater range of frequencies once it is tuned (see paragraph 0012). Further, the dipole antenna of Mass et al. does not require any special implantation procedures and is a rigid structure that is resistant to breakage or deformation (see paragraph 0011). Although Mass et al. describes that the disclosed

dipole antenna configuration can be utilized in various implantable medical devices, including physiological monitors (see paragraph 0013), Mass et al. fails to specifically teach that the implantable medical device may encompass a position sensor. However, implantable position sensors for detecting the physical orientation of the implanted medical device within the body are well known in the art (see, for example, U.S. Patent No. 4,846,195). Such position information may be utilized for delivering therapy to the patient. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to combine the teachings of Mass et al. and Alt in order to provide an implantable position sensor with a greater bandwidth and a telemetry configuration that is resistant to breakage or deformation.

In addition, Mass et al. and Alt fail to teach that the position signal, which would necessarily be generated by the position sensor, is indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw, and roll orientations. Ben-Haim teaches a system for position sensing that produces three location coordinates and three orientation coordinates (a six-dimensional position signal) (see Abstract). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the position sensor of Mass et al./Alt such that the position sensor generates a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw, and roll orientations as taught by Ben-Haim et al. in order to provide more detailed position information, that is, information relating to both the position and orientation of the sensor.

With respect to claim 2, Mass et al. discloses an IMD in which the electrically conductive housing portions of the casing form a dipole antenna. Mass et al. discloses that the electrically conducting portions (101a and 101b) of the housing are separated by a layer of insulating material 102 (see paragraph 0013), but fails to specifically disclose that the insulating material may be a ceramic material or a plastic material. Both ceramics and plastic materials are well known insulating materials used in the medical device art. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to utilize either ceramic or plastic material as insulating material 102 of Mass et al. since both materials are well known in the medical device art for their insulating characteristics.

With respect to claims 3, 5, 8, 10-11, 18, 23, and 26-27, please see comments above relating to the description of Mass et al.

6. Claims 1-2, 4-5, 8, and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,861,019 ("Sun et al.") in view of U.S. Patent No. 4,846,195 ("Alt") and further in view of U.S. Patent Application Publication 2002/0065455 ("Ben-Haim et al.").

As described above, Sun et al. discloses an IMD in which a microstrip patch antenna is conformed to the exterior housing of the IMD. Sun et al. teaches that forming the antenna on the exterior of the IMD housing provides a number of advantages, including enhanced data bit rates, low error rates over a long distance, minimization of power consumption during uplink and downlink telemetry transmissions,

and near hemispheric coverage (see col. 5, lines 30-45). Although Sun et al. describes that the IMD antenna configuration can be utilized in various implantable medical devices, including physiological monitors (see col. 4, line 64 - col. 5, line 10 and col. 8, lines 1-12)), Sun et al. fails to specifically teach that the implantable medical device may encompass a position sensor. However, implantable position sensors for detecting the physical orientation of the implanted medical device within the body are well known in the art (see, for example, U.S. Patent No. 4,846,195). Such position information may be utilized for delivering therapy to the patient. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to combine the teachings of Sun et al. and Alt in order to provide an implantable position sensor with enhanced data bit rates, low error rates over a long distance, minimization of power consumption during uplink and downlink telemetry transmissions, and near hemispheric coverage.

In addition, Sun et al. and Alt fail to teach that the position signal, which would necessarily be generated by the position sensor, is indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw, and roll orientations. Ben-Haim teaches a system for position sensing that produces three location coordinates and three orientation coordinates (a six-dimensional position signal) (see Abstract). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the position sensor of Sun et al./Alt such that the position sensor generates a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw, and roll orientations as taught by Ben-Haim

et al. in order to provide more detailed position information, that is, information relating to both the position and orientation of the sensor.

With respect to claims 2, 4, 8, 10-11, 18, 23, and 26-27, please see comments above relating to the description of Sun et al.

7. Claims 12-13 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,447,448 ("Ishikawa et al.") in view of U.S. Patent Application Publication 2002/0095195 ("Mass et al.") or U.S. Patent No. 5,861,019 ("Sun et al."), and further in view of U.S. Patent Application Publication 2002/0065455 ("Ben-Haim et al.").

Ishikawa et al. teaches an implantable orthopedic sensor in the shape of a spherical ball which can be implanted within a metallic, orthopedic insert for sensing various physiological and positional parameters, such as monitoring the integrity of a implant coupling, the temperature generated by action of a mechanical joint, or pressure exerted on the joint interface (see Fig. 3 and associated text at col. 7, lines 1-22). The orthopedic sensor (i.e., ball 110) includes a processor 140, a radio communication circuit 150, and one or more sensors 160. Ishikawa et al. fails to disclose that conductive material of the outer surface of the casing serves as an antenna for transmitting the signal to a receiver outside the body. Both Mass et al. and Sun et al. disclose an IMD, such as a physiological monitor, in which electrically conductive housing portions of the IMD casing form an antenna. Mass et al. teaches that forming the antenna from conductive portions of the housing results in a greater bandwidth,

which is easier to tune and is usable over a greater range of frequencies once it is tuned (see paragraph 0012). Further, the dipole antenna of Mass et al. does not require any special implantation procedures and is a rigid structure that is resistant to breakage or deformation (see paragraph 0011). Sun et al. teaches that forming the antenna on the exterior of the IMD housing provides a number of advantages, including enhanced data bit rates, low error rates over a long distance, minimization of power consumption during uplink and downlink telemetry transmissions, and near hemispheric coverage (see col. 5, lines 30-45). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the implantable orthopedic sensor of Ishikawa et al. such that electrically-conductive housing portions of the sensors form an antenna as taught by Mass et al. or Sun et al. in order to provide the orthopedic sensor with the telemetry advantages disclosed in Sun et al. or Mass et al.

As mentioned above, Ishikawa et al. teaches that the implantable orthopedic sensor (i.e., ball 110) may be used for various for physiological monitoring using the one or more sensors 160. Some examples of physiological conditions that can be measured include position (see col. 6, lines 45-65). However, Ishikawa et al. fails to teach that the position signal, which would necessarily be generated by a position sensor, is indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw, and roll orientations. Ben-Haim teaches a system for position sensing that produces three location coordinates and three orientation coordinates (a six-dimensional position signal) (see Abstract). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the

implantable orthopedic sensor of Ishikawa et al. such that the position sensor generates a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw, and roll orientations as taught by Ben-Haim et al. in order to provide information relating to both the position and orientation of the sensor.

With respect to claim 19, when the electrically conductive casing (as modified by Mass et al. above) is placed in contact with the metallic orthopedic hip prosthesis (see Fig. 3 of Ishikawa et al), the gain of the antenna will necessarily be increased in transmitting the signal.

Response to Arguments

8. With respect to the rejections based on Mass et al., Applicant's arguments have been considered but are either not persuasive or moot in view of the new ground(s) of rejection. In particular, Applicant argues that Mass et al. does not teach or suggest an IMD having a casing comprising an insulating material surrounding a conductive area. However, as described above, Examiner considers the insulating material 102 to "surround" the metallic device housing halves 101a and 101b because the insulating material separates the housing portions from each other, and thus necessarily encloses or encompasses the entire, bottom perimeter or edge of each half.

In addition, Applicant argues that Mass et al. fails to disclose a transmitter adapted to generate a position signal indicative of six-dimensional position and orientation. Initially, with respect to claim 1, Examiner notes that such claim limitation is intended use only. As described above, the IMD of Mass et al. is capable of

transmitting any type of sensed signal and thus anticipates the claim. In addition, such arguments are moot in view of the new grounds of rejection (Examiner provided an alternate, 103 obviousness-type rejection based on Mass et al. in view of U.S. Patent No. 4,846,195 ("Alt") and further in view of U.S. Patent Application Publication 2002/0065455 ("Ben-Haim et al.")).

9. With respect to the rejections based on Sun et al., Applicant's arguments have been considered but moot in view of the new ground(s) of rejection. Applicant argues that Sun et al. fails to disclose a transmitter adapted to generate a position signal indicative of six-dimensional position and orientation. Initially, with respect to claim 1, Examiner notes that such claim limitation is intended use only. As described above, the IMD of Sun et al. is capable of transmitting any type of sensed signal and thus anticipates the claim. In addition, such arguments are moot in view of the new grounds of rejection (Examiner provided an alternate, 103 obviousness-type rejection based on Sun et al. in view of U.S. Patent No. 4,846,195 ("Alt") and further in view of U.S. Patent Application Publication 2002/0065455 ("Ben-Haim et al.")).

With respect to the rejections based on Ishikawa et al., Applicant's arguments have been considered but are either not persuasive or moot in view of the new ground(s) of rejection. In particular, Applicant argues that the semiconductor ball 110 of Ishikawa et al. has a completely different arrangement than the insulating material surrounding a conductive area. However, as described above, relies on the teaching

reference Mass et al. or Sun et al. for these claim elements. Both Mass et al. and Sun et al. disclose an IMD, such as a physiological monitor, in which electrically conductive housing portions of the IMD casing form an antenna. Mass et al. teaches that forming the antenna from conductive portions of the housing results in a greater bandwidth, which is easier to tune and is usable over a greater range of frequencies once it is tuned (see paragraph 0012). Further, the dipole antenna of Mass et al. does not require any special implantation procedures and is a rigid structure that is resistant to breakage or deformation (see paragraph 0011). Sun et al. teaches that forming the antenna on the exterior of the IMD housing provides a number of advantages, including enhanced data bit rates, low error rates over a long distance, minimization of power consumption during uplink and downlink telemetry transmissions, and near hemispheric coverage (see col. 5, lines 30-45). Examiner maintains that it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the implantable orthopedic sensor of Ishikawa et al. such that electrically-conductive housing portions of the sensors form an antenna as taught by Mass et al. or Sun et al. in order to provide the orthopedic sensor with the telemetry advantages disclosed in Sun et al. or Mass et al.

In addition, Applicant argues that Ishikawa et al. fails to disclose a transmitter adapted to generate a position signal indicative of six-dimensional position and orientation. Such arguments are moot in view of the new grounds of rejection based in part on U.S. Patent Application Publication 2002/0065455 ("Ben-Haim et al.").

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRK
9/7/06

George Manuel
Primary Examiner